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# Cognitive Behavioural Therapy Informed Physiotherapy for Patellofemoral Pain: A feasibility study

## Introduction

Patellofemoral pain (PFP) accounts for 11% of knee complaints seen in general practice (van Middlekoop et al, 2008). Exercise therapy is a key physiotherapy management strategy which reduces pain and improves function in the short-term in PFP patients (van der Heijden et al, 2015) but >50% of adults report persistent symptoms (Lankhorst et al, 2016). Increased anxiety, depression, catastrophising and pain-related fear of movement are associated with persistent symptoms in PFP patients (MacLachlan et al, 2017) and reduced catastrophising and anxiety following exercise therapy predicted reduced knee pain and / or disability (Domenech et al 2014).

Cognitive behavioural therapy (CBT) is a psychological intervention which recognises the cognitive, emotional and behavioural contribution to the pain experience and aims to modify these factors to improve patients' pain coping skills (O'Keefe & Somers, 2014). It is a promising approach for persistent musculoskeletal pain conditions especially when combined with exercise-based physiotherapy (Babatunde et al, 2017). However, the use of CBT informed physiotherapy has not been investigated in PFP management.

The aim of this study was to evaluate the feasibility and acceptability of a two-arm, single-blind, randomised controlled trial comparing CBT informed physiotherapy to exercise-based physiotherapy for people with PFP consistent with Consolidated Standards of Reporting Trials (CONSORT) guidelines (Schulz et al, 2010). Specific feasibility and acceptability objectives explored a) participant recruitment and retention; b) completion of measures; and c) participant attendance at the CBT informed physiotherapy intervention d) participant satisfaction (Table1).

## Methods

This prospective single blind two-arm parallel group randomised controlled feasibility trial was approved by the local university research ethics committee on 20/07/2017 (LRU-16/17-5042).

## Participants

Potentially eligible participants were identified from an inner-city university campus and local sports clubs in the United Kingdom using email circulars and poster advertisements. Interested potential participants were screened by researchers and enrolled onto the study if they matched the inclusion criteria (Esculier et al, 2018);

- People with non-traumatic anterior or retropatellar pain present for  $\geq 12$  weeks
- Aged 18-45 years
- Self-reported pain  $\geq 3/10$  on the Numerical Rating Scale during  $\geq 2$  physical activities such as running and stair negotiation
- Pain on at least 2 of 3 physical tests; palpation of the peripatellar tissues, resisted knee extension or squatting
- Self-reported disability  $\leq 85/100$  on Anterior Knee Pain Scale

Adults were not enrolled if they had;

- Other knee pathologies including meniscal pathologies or knee surgery (either self-reported or identified on physical examination)
- Self-reported concurrent lower limb injury/pathology
- Self-reported rheumatological, neurological or degenerative diseases
- Physiotherapy treatment for PFP in last 6 months
- A score of  $\geq 11$  on the anxiety or depression subscale of the Hospital Anxiety and Depression Scale
- Were pregnant

## Sample Size & Randomisation

As this was a feasibility study, a power calculation was not conducted but a sample of 20 participants was targeted (Sim & Lewis, 2012). Potential participants attended an appointment to confirm eligibility, provide written informed consent and complete a baseline assessment. Subsequently, participants were randomly allocated to either CBT informed physiotherapy (active) or exercise-based physiotherapy care (comparison) group by simple balanced two-way randomisation. The randomisation sequence was determined using an online random number generator ([www.sealedenvelope.com](http://www.sealedenvelope.com)) to produce an output of 10 allocations per group and the allocation codes were placed in separate sealed opaque

envelopes prior to trial initiation. Each participant chose one envelope to determine group assignment.

## Interventions

### Comparison Group

The comparison group received 6 physiotherapy sessions (30 minutes duration consistent with usual physiotherapy practice) delivered over 8 weeks. This included a protocolised physical examination and progressive exercise programme which was tailored to the participants' impairments. (Barton et al, 2015; van Linoschoten et al, 2006) (see Table 2).

### Active Group

The active group received a 6 session CBT informed physiotherapy intervention (45 minutes duration) delivered over 8 weeks. The intervention aimed to reduce knee pain related disability, improve coping skills and modify unhelpful pain beliefs. The intervention was developed by health psychologists and experienced musculoskeletal physiotherapists, informed by the CBT literature (Johnstone et al, 2004). It included a protocolised physical examination and progressive exercise programme which was tailored to the participants' impairments (Table 2) and a tailored CBT informed consultation to address the participants' needs and goals (Table 3). It was delivered by one of two physiotherapists who received 6 hours face to face training in CBT principles provided by two health psychologists experienced in the CBT approach and 10 hours guided study.

## Clinical measures

Self-reported sociodemographic and clinical characteristics (sex, age, height, weight, knee symptom duration) were collected using a bespoke questionnaire at baseline. Six self-reported valid and reliable questionnaires were administered at baseline and post intervention (8 weeks) by an assessor blind to participants' group allocation.

**Knee-related disability** during daily and sporting activities was assessed using the 13-item Anterior Knee Pain Scale (AKPS) (Kujala, 1993). Lower scores indicate greater disability (range 0-100) and the minimal clinically important difference (MCID) is 10 points (Crossley et al, 2004).

**Knee pain intensity** over the previous week was assessed using a 0-100mm Visual Analogue Scale (VAS) (anchors: no pain- worst possible pain). Higher scores reflect higher pain intensity (MCID – 2 points) (Crossley et al, 2004).

**Low mood and anxiety** was assessed using the 14 item Hospital Anxiety and Depression Scale (HADS) with separate subscales for anxiety and depression. Higher scores indicate greater emotional distress (range 0-21) (Zigmond and Snaith, 1983; Brennan et al, 2010). The exclusion criteria include subscale scores  $\geq 11$  as these suggest a major depressive/anxiety episode (Hung et al, 2011) requiring other management.

**Catastrophising** was assessed using the 13 item Pain Catastrophizing Scale (PCS; 5 point likert scale; 0='not at all' - 4='all the time') Higher scores reflecting more catastrophising thoughts (range 0-52, MCID – 5 points) (Osman et al, 2000; Schütze et al, 2018).

**Pain related fear of movement** was evaluated using the 13 item Tampa Scale of Kinesiophobia (TSK; 4 point likert scale 1='strongly disagree – 4='strongly agree'). Higher scores indicated greater kinesiophobia (range 17 – 68) MCID-8 points) (Lüning Bergsten et al, 2012; Swinkels-Meewisse et al, 2003; Miller et al, 1991).

**Health-related Quality of Life** was measured using the 5 item EQ-5D assessing different dimensions; health, mobility, self-care, usual activities, pain / discomfort and anxiety / depression. An overall index score is calculated with scores at 0 for death and 1 for perfect health (EuroQol Group, 1990).

Following intervention, **satisfaction** was assessed using the reliable and valid 10-item Consultation And Relational Empathy (CARE) questionnaire (5 point likert scale 'poor' – 'excellent') (Bikker et al, 2015; Mercer et al, 2004). A higher score indicates greater perceived empathy and quality of care received (range 0-50).

## Analysis

Sociodemographic and clinical characteristics are presented as means  $\pm$ SD for continuous variables. The rate of participant recruitment, retention and attendance at the intervention sessions and the proportion of participants with complete data was calculated (%).

Effect sizes for within group changes and between group difference at 8 weeks were calculated using Hedges'  $g$  (Lenhard & Lenhard, 2016) and categorised as small (0.01-0.19), medium (0.2–0.79) or large ( $\geq 0.8$ ) (Cohen's 1988).

## Results

### **Recruitment and retention:**

Thirty five people responded to the advertisement between February to May 2018. Following screening 15 eligible potential participants were identified and 11 (73.3%) participants were enrolled onto the study and randomised (mean age  $\pm$ SD years,  $26.6 \pm 6.7$ ; 9 females) (Figure 1). There were no substantial between group differences in any sociodemographic or clinical outcomes (Table 4). Nine of the 11 (81.8%) of participants completed the trial, both participants who were lost to follow-up were from the comparison group.

**Completion of study measures:** At baseline the sociodemographic and clinical measures and AKPS and HAD questionnaires were collected for 11 (100%) participants but the TSK, PCS, VAS and EQ-5D was collected for 10 (90.9%) participants only, due to assessor error. 100% of participants who completed the trial completed all the questionnaires at 8 weeks.

**Attendance at interventions sessions:** Overall, participants attended 59/66 sessions (89.4%; active group 100%, comparison group 80.6%).

**Satisfaction:** The overall satisfaction score was  $49.2 \pm 1.1$  (active group:  $50.0 \pm 0.0$ , comparison group  $49.6 \pm 0.8$ ) on the CARE index.

### **Clinical measures:**

There were improvements in pain, disability, catastrophising, fear of movement and quality of life in both groups over time. There were also improvements in anxiety and depression in the comparison group but not the active group (Table 4). There were medium to large effect sizes favouring the active group for pain, disability, catastrophising and fear of movement but small effect sizes for anxiety and low mood favouring the comparison group.

## Discussion

This study demonstrated the feasibility and acceptability of a two-arm randomised controlled

trial comparing CBT informed physiotherapy with exercise-based physiotherapy for people with PFP. Criteria reflecting recruitment, retention, completion of measures and adherence to and satisfaction with the interventions were achieved. Results additionally inform aspects of the protocol which could be improved.

In our 3-month recruitment period, we identified 15 eligible people with PFP, similar to other studies (Smith et al, 2019). This suggests that our recruitment strategy is promising and a recruitment rate of 4 participants per month from a university and local sports clubs would be plausible in a full trial. We did not recruit patients referred for physiotherapy for PFP, due to study time constraints, and a greater recruitment rate is likely if recruitment was extended to healthcare facilities. We recruited >70% of eligible participants and a high proportion completed the study, similar to other studies (Collins et al, 2008; van Linschoten et al, 2018). This recruitment and retention data satisfied the feasibility success criteria.

While the overall study completion rate was 82%, the completion rate was greater in the active group. One participant withdrew from the study due to work constraints. Our study participants were aged between 18-45 years, similar to other studies (Esculier et al, 2018). Working age participants are likely to have competing commitments such as employment or other caring responsibilities so a full trial should offer a range of appointment times to optimise participant accessibility. The amount of missing data was <10% at all time points, however, one participant did not complete four questionnaires due to assessor error and more rigorous outcome assessor training is warranted.

Attendance at intervention sessions was high overall (>85%), with greater attendance in the active group (100%) versus the comparison group (81%). This was congruent with the high participant satisfaction reported and suggest that participants found the interventions acceptable. However, we did not interview the participants', therapists' or assessor to gain a deeper understanding of their experiences and views of the intervention and the trial.

Whilst our study was not powered to detect differences in our clinical outcomes, our preliminary data suggest that there were promising improvements in pain, disability, catastrophising and fear of movement but not mood following the active intervention. These improvements were greater than the minimal clinically important differences for VAS, AKPS and PCS and suggest that our intervention warrants further investigation.

This study had several strengths; it evaluated a clinically relevant intervention, the outcome assessor was blind to participant group allocation and several valid and reliable patient reported outcome measures were used. The interventions were delivered by physiotherapists who received training from health psychologists on embedding CBT principles in the physiotherapy management of PFP. Additionally, clear success criteria were identified to justify progression to a full trial.

This study had some limitations; we did not reach our target sample size due to time constraints and so the numbers of participants included in our analysis were small. However, this preliminary data still provides information on the feasibility and acceptability of a future trial. No qualitative research was undertaken to explore experience of the trial or intervention. However, anecdotally, our participants suggested that the interventions were acceptable and the trial physiotherapists reported that the active intervention was easy to deliver and that it could be integrated into physiotherapy practice.

## Conclusion

This study demonstrated that a trial investigating CBT informed physiotherapy versus exercise-based physiotherapy care is feasible and that our intervention and trial protocol was broadly acceptable. The CBT intervention improved key outcomes in people with PFP suggesting that the intervention warrants further investigation.

**Word count: 1998**



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## Tables

**Table 1** Study feasibility and acceptability objectives, criteria and outcomes

Feasibility objectives	Feasibility criteria	Feasibility outcome
1) to evaluate participant recruitment and retention	1.1. At least 60% recruitment of eligible participants will be achieved	1.1 Achieved (n=11/15, 73% recruitment rate)
	1.2. Study retention at 8 week follow-up will be at least 60%	1.2 Achieved (82% study retention at 8 week follow-up)
2) to explore the completion & suitability of the proposed measures	2.1. Missing data at each time point will be less than 10%.	2.1 Achieved (Missing data <10% at baseline and 0% at 8 week follow-up for those retained on the trial)
	2.2 Sufficient data will be collected to explore change	2.2 Achieved (for most measures small to large effect sizes for within and between group comparison)
3) to explore participant attendance at the interventions	3.1 At least 60% of participants will complete all intervention sessions.	3.1 Achieved (89% attendance at intervention sessions)
4) to evaluate participant satisfaction	4.1 The CARE score will be $\geq 46$ (Mercer et al, 2004)	4.1 Achieved (both interventions scored > 49 on CARE)

**Abbreviations:** CARE questionnaire - Consultation And Relational Empathy questionnaire

**Table 2** The exercise-based physiotherapy intervention

Target region for strengthening †	Potential exercises and progression of exercises	Dosage ‡‡
<b>Quadriceps</b>	Level 1 – Active straight leg raise, Resisted knee extension in sitting (theraband resistance), mini-squat against the wall (progression to no wall), and step-up Level 2 – Resisted knee extension in sitting (increased theraband resistance), lunges and single leg mini-squat Level 3 – Single leg full squat, step-ups on high step, step-downs, squat jumps, single leg hops	3 sets of 10-12 repetitions performed 4-6 times weekly
<b>Gluteus maximus</b>	Level 1 – Hip extension in prone-lying or 4 point kneeling, bridging and transferring from sitting to standing from a high chair. Level 2 – Hip extension in standing (theraband resistance), transferring from sitting to standing from a low chair, single leg bridging, static lunge Level 3 – Step-ups on a high step, jumps, lunges (theraband resistance)	3 sets of 10-12 repetitions performed 4-6 times weekly
<b>Gluteus medius</b>	Level 1 – Hip abduction in side-lying and single leg stand (with knee flexed $\approx 20^\circ$ ) Level 2 – Hip abduction in standing (theraband resistance), side-stepping theraband resistance), side step-up and single leg stand (with knee flexed $\approx 20-40^\circ$ ) Level 3 – Single leg stand (pushing thigh into wall), single leg mini-squat, side plank and single leg stand (with knee flexed $\approx 60-90^\circ$ )	3 sets of 10-12 repetitions performed 4-6 times weekly
<b>Hamstrings</b>	Level 1 – Resisted knee extension in sitting or standing (theraband resistance), bridging and bodyweight deadlift Level 2 – Resisted knee extension in prone-lying (theraband resistance) and single leg bodyweight deadlift Level 3 – Norwegian hamstring curl and single leg bridging (leg lift from a high surface)	3 sets of 10-12 repetitions performed 4-6 times weekly
<b>Tibialis posterior and intrinsic foot muscles</b>	Heel raise (progression to heel raise on a step) Arching sole of foot	3 sets of 10-12 repetitions performed 4-6 times weekly
<b>Target region for stretching§</b>		<b>Dosage§§</b>
<b>Lower limb stretches</b>	Quadriceps, hamstrings, hip flexors, calf muscles	2 repetitions of a 10-30 second hold performed daily

†The target region for strengthening was identified following physical examination and exercises were chosen from the bank and progression was determined by assessment of 10 RM.

‡Dosage of exercises generally followed the American College of Sports Medicine principles for strength training (Ratamess et al, 2009)

§The target region for stretching was identified following physical examination and exercises were chosen from the bank and §§ dosage followed the American College of Sports Medicine principles for flexibility exercises (Garber et al, 2011)

**Table 3** The Cognitive Behavioural Therapy Informed Physiotherapy intervention

Session 1
Introduction to CBT: Exploration of thoughts & beliefs about pain & their influence on behaviour
Session 2:
Cognitive restructuring: Acknowledging automatic thoughts & rationalizing maladaptive thoughts Goal setting
Session 3:
Pacing & planning activity Pleasant activity scheduling
Session 4:
Problem solving: Forming strategies to address barriers to improvement such as low exercise adherence Optional Relaxation techniques including mindfulness and breathing
Session 5:
Assess progress: Review goals and exercises
Session 6:
Problem solving: Dealing with setbacks and relapse prevention Maintain activity & review
<i>Typical content for CBT informed physiotherapy – tailored to an individuals' needs and goals. Timeframe for each session was approximately 15 minutes.</i>

**Table 4** Sociodemographic and secondary outcomes for patellofemoral participants

	Active Group				Comparison Group				Effect size† (Between group at 8 weeks)
	Mean (SD)								
Outcomes	Baseline	8 weeks	Within group change	Effect size† (within group)	Baseline	8 weeks	Within group change	Effect size† (within group)	
Age (years)	28.2 (8.1)				25.3 (5.8)				
Body mass (kg)	67.0 (15.7)				69.6 (14.2)				
Height (m)	1.7 (8.7)				1.7 (3.4)				
Duration of symptoms (weeks)	122.2 (69.0)				67.5 (58.4)				
VAS (mm)	29.0 (16.0)	5.0 (5.0)	-24.0 (12.9)	1.8	37.3 (19.4)	38.2 (24.7)	0.8 (18.4)	<0.1	1.8
AKPS	71.0 (11.4)	89.2 (10.5)	18.2 (16.5)	1.5	71.0 (10.8)	73.3 (17.2)	2.3 (18.6)	0.2	1.1
TSK	38.6 (4.3)	31.4 (4.2)	-7.2 (4.7)	1.5	41.7 (7.5)	37.7 (5.0)	-4.0 (4.5)	0.6	1.4
PCS	19.6 (7.1)	8.0 (4.2)	-11.6 (7.7)	1.8	12.7 (6.5)	8.8 (6.4)	-3.8 (7.7)	0.6	0.1
HAD-A	6.0 (3.2)	9.6 (7.7)	3.6 (7.3)	0.6	5.5 (1.4)	0.8 (1.5)	-0.2 (4.2)	3.0	1.7
HAD-D	2.4 (0.9)	6.0 (5.3)	3.6 (5.2)	0.9	5.3 (3.3)	2.3 (3.1)	1.5 (3.4)	0.9	0.9
EQ5D	0.7 (0.1)	0.8 (0.1)	0.1 (0.1)	0.9	0.7 (0.1)	0.8 (0.1)	<0.1 (0.1)	0.9	0.0

**Abbreviations:** VAS Visual Analogue Scale; AKPS, Anterior Knee Pain Scale; TSK, Tampa Scale of Kinesiophobia; PCS, Pain Catastrophising Scale; HAD-A, HAD-D, Anxiety and Depression subscales respectively of the Hospital Anxiety & Depression Questionnaire.

† Hedge's g.

## Figure Legend

**Figure 1** Study flow diagram for patellofemoral pain participants following Consort Statement (2010)